

Notice of Allowability

Application No.

10/624,534

Applicant(s)

WOLFINBARGER ET AL.

Examiner

Art Unit

Sandra Saucier

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments and arguments filed 2/16/07.
2. ☒ The allowed claim(s) is/are 56-58,60-65,70,71,73-76,78,80,86-90,96-99,102,108,109 and 121-142.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Sandra Saucier
Primary Examiner
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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with S. Wardwell on 10/24/07.

The application has been amended as follows:

56. A process for preparing an acellular soft tissue graft comprising:

extracting at least one soft tissue sample with a buffered alkaline extraction solution which contains at least one nonionic detergent and at least one endonuclease, and which is hypotonic to the cells in said soft tissue sample,

washing said extracted tissue in a first washing solution comprising water to produce a first washed tissue,

treating said first washed tissue with a first processing solution comprising an anionic detergent to produce a first processed tissue,

washing said first processed tissue in a second washing solution comprising water to produce a second washed tissue and,

storing said second washed tissue in a storage solution comprising at least one decontaminating agent and water.

57. The process of claim 56, wherein said extraction solution has an alkaline pH.

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60. The process of claim 56, wherein said first processing solution comprises at least one buffer, has an alkaline pH and an osmolality which is hypertonic to the cells in said soft tissue sample.

108. An acellular tissue graft prepared by the process of claim 56, wherein said anionic detergent is sodium dodecylsulfate (SDS) and wherein the second washed tissue contains SDS in about 0.001% by weight SDS/wet weight of tissue.

109. A process for preparing an acellular soft tissue graft comprising:

extracting at least one soft tissue sample with a buffered alkaline extraction solution which contains at least one nonionic detergent and at least one endonuclease, and which is hypotonic to the cells in said soft tissue sample,

washing said extracted tissue in a first washing solution comprising water to produce a first washed tissue,

treating said first washed tissue with a first treating solution comprising a solution which is hypertonic to the cells in said soft tissue sample and contains an anionic detergent and salt to produce a first processed tissue, ,

washing said first processed tissue in a second washing solution comprising water to produce a second washed tissue,

treating said second washed tissue with a second treating solution which comprises a salt and which is hypertonic to the cells in said soft tissue sample, to produce a second treated tissue,

washing said second treated tissue in at least one third washing solution comprising water to produce a third washed tissue and,

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storing said third washed tissue in a storage solution comprising at least one decontaminating agent and water.

121. An acellular tissue graft prepared by the process of claim 56 or claim 109 or claim 141 or claim 142.

135. The tissue graft of claim 121, wherein the stored tissue comprises less than 20 wt% calcium ion precipitated anionic detergent.

136. The tissue graft of claim 121, wherein the stored tissue comprises from about 0.2 wt% to about 2.0 wt% calcium ion precipitated anionic detergent.

137. The process of claim 141 or 142, wherein the stored tissue comprises at least 1.0 μ mole calcium ion precipitated anionic detergent/mg weight of tissue.

138. The process of claim 141 or 142, wherein the stored tissue comprises from about 0.1wt% to about 10 wt% calcium ion precipitated anionic detergent.

139. The process of claim 141 or 142, wherein the stored tissue comprises less than 20 wt% calcium ion precipitated anionic detergent.

140. The process of claim 141 or 142, wherein the stored tissue comprises from about 0.2wt% to about 20 wt% calcium ion precipitated anionic detergent.

141. A process for preparing an acellular soft tissue graft comprising:

extracting at least one soft tissue sample with a buffered alkaline extraction solution which contains at least one nonionic detergent and at least one endonuclease, and which is hypotonic to the cells in said soft tissue sample,

washing said extracted tissue in a first washing solution comprising water to produce a first washed tissue,

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treating said first washed tissue with a first treating solution comprising a solution which is hypertonic to the cells in said soft tissue sample and contains an anionic detergent and salt to produce a first processed tissue, ,

washing said first processed tissue in a second washing solution comprising water to produce a second washed tissue,

treating said second washed tissue with a second treating solution which comprises a salt and an anionic detergent which is sodium dodecylsulfate and which is hypertonic to the cells in said soft tissue sample, to produce a second treated tissue,

washing said second treated tissue in at least one third washing solution comprising water and a calcium salt to produce a third washed tissue and,

storing said third washed tissue in a storage solution comprising at least one decontaminating agent and water.

142. A process for preparing an acellular soft tissue graft comprising:

extracting at least one soft tissue sample with a buffered alkaline extraction solution which contains at least one nonionic detergent and at least one endonuclease, and which is hypotonic to the cells in said soft tissue sample,

washing said extracted tissue in a first washing solution comprising water to produce a first washed tissue,

treating said first washed tissue with a first processing solution comprising an anionic detergent which is sodium dodecylsulfate to produce a first processed tissue,

washing said first processed tissue in a second washing solution comprising water and a calcium salt produce a second washed tissue and,

storing said second washed tissue in a storage solution comprising at least one decontaminating agent and water.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to be 'Sandra Saucier', with a stylized, cursive script.

Sandra Saucier
Primary Examiner
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